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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,841	01/15/2004	Michael Wayne Graham	0687/74768-AA/JPW/GJG/JRM	8757

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COOPER & DUNHAM, LLP
30 Rockefeller Plaza
20th Floor
NEW YORK, NY 10112

EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

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01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,841	GRAHAM ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *172,176-188,190-197,199,200,202-209 and 211* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *172,176-188,190-197,199,200,202-209,211* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The office action mailed on 1/6/09 has been vacated and replaced with the instant office action. The IDS and PTO-892 were already mailed with the office action mailed on 1/6/09 and will not be mailed with the instant office action.

Election/Restrictions

This application contains Viral RNA protein and Viral DNA polymerase in claims 172, 188, and 200 drawn to an invention nonelected with traverse in the reply filed on 12/29/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

With respect to the term "stuffer fragment", the instant specification defines the term (see page 19, line 14 to page 20, line 14).

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al (US 6,506,559, cited on a PTO-1449) taken with Cowsert et al. (US 5,580,767, of record).

The 102(e) reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Fire teaches a vector comprising a construct comprising a promoter operably linked to a nucleotide sequence comprising dsRNA comprising a sense strand and an antisense strand of the target gene (columns 4 and 9). The sequence can comprise one or more strands of the nucleotide sequence (column 4). The dsRNA may be formed by a single self-complementary RNA strand or two complementary RNA strands (column 7). A single self-complementary strand would indicate that the vector comprising nucleotides sequences would read on a stuffer between the sequences. In such a molecule having several nucleotide sequences, an arbitrary number of nucleotides associated with the inherent hairpin region of the strand can be arbitrarily considered to be a stuffer fragment that links 25 complementary base pair. This construct could have stuffer regions of one or more strands of the nucleotide sequence containing nucleotide bases on the arbitrary designation of what is, and what is not, the stuffer sequence. The construct comprises a regulatory region including polyadenylation (columns 8-9). The nucleotide sequence may be at least 25 or 50 bases (column 8). The vector can be introduced into a cancerous cell, including cancer cells find in humans (column 9-10). A viral vector or lipid mediated carrier transport can be used as the vector (column 9). Fire teaches using phagemid clones to produce the RNA (column 18). One of ordinary skill in the art understands that phagemid clones can be used for double stranded replication. The cell can comprise a target gene at risk from a pathogen including HIV (two copies of positive single-stranded RNA) or can be from several different types of animals (columns 4, 8, and 10). The structural gene can be less than 2.0 kilobases

(table 1 and Figure 1). However, Fire does not specifically teach targeting RNA polymerase of a viral gene.

However, at the time the invention was made, Cowsert teaches antisense oligonucleotides for inhibiting RNA polymerase (column 3).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a virus. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a lentivirus. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of an immunodeficiency virus. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a virus, wherein the gene is in an exon. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus by targeting the exon.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a virus, wherein the construct is no more than 0.5-2.0 kilobases. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising a construct comprising a structural gene encoding RNA polymerase of a virus, wherein the construct has a stuffer fragment of 10-50, 50-100, or 100-500 nucleotides in length. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus by targeting multiple regions of the virus. In such a

construct, an arbitrary number of nucleotides associated with the inherent hairpin region of the RNA strand can be arbitrarily considered to be a stuffer fragment that links 25 complementary base pair. This molecule could have stuffer regions of one or more strands of the nucleotide sequence containing nucleotide bases on the arbitrary designation of what is, and what is not, the stuffer sequence. See In re Aller, Id.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Fire taken with Cowsert, namely to produce an isolated mammalian cell comprising liposome or viral particle comprising a construct comprising a structural gene encoding RNA polymerase of a virus. One of ordinary skill in the art would have been motivated to combine the teaching to improve and study the efficiency of inhibiting the virus and to successfully deliver the construct to a cell of interest.

In view of the teaching of Fire (columns 8-9) and Cowsert (column 3), one of ordinary skill in the art would have had a reasonable expectation of success of producing the mammalian cell comprising the dsRNA construct. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." See ***KSR v. Teleflex***, 550 U.S. ___, 127 S. Ct. 1727 (2007).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/14/08 have been fully considered but they are not persuasive.

In response to applicant's argument that the instant claims and the claims from Fire are patentably distinct because the limitation "a repeating sequence of only 20-30 consecutive nucleotides, in the context of mammalian cells" is neither claim nor disclosed by Fire and the claims of Fire are directed to "separate strands", the argument is not found persuasive because 37 CFR 41.203. Declaration states:.

(a) Interfering subject matter. An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.

This is the case here, the claims from Fire render obvious the subject matter of the instant claims.

In response to applicant's argument that the Fire does not enjoy a priority date before the instant application because the provisional of Fire teaches less than the patent of Fire and the last office action cites numerous portions of Fire et al. Patent which do not appear in the Fire et al. provisional, the argument is not found persuasive because the argument does not address whether or not Fire teaches the claimed product. Furthermore, the portions of Fire et al. patent that teach the claimed product are supported in the Fire et al. provisional. The applicant has not specifically pointed out what portions of the 102(e) rejection are not supported by the Fire et al. provisional.

In response to applicant's argument that Fire and Cowsert do not disclose synthetic genes with a stuffer fragment as recited in the amended claims and a repeating sequence of only 20-30 consecutive nucleotides in length, the argument is not found persuasive because Fire teaches that the nucleotide sequence may be at least 25

bases (column 8), the dsRNA may be formed by a single self-complementary RNA strand (column 7), and the nucleotide sequence can contain one or more nucleotide sequences (column 4). "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments." See Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). In such a molecule, an arbitrary number of nucleotides associated with the inherent hairpin region of the strands can be arbitrarily considered to be a stuffer fragment that links 25 complementary base pair. This molecule could have stuffer regions of one or more strands of the nucleotide sequence containing nucleotide bases on the arbitrary designation of what is, and what is not, the stuffer sequence.

Applicants' argument directed to Paul teaching an unexpected property of the claimed invention is not found persuasive because the citation of lines 6-8 of the abstract of Paul is directed to another reference that teaches using siRNA duplexes, not double-stranded synthetic gene as claimed. The unexpected result has to commensurate in scope with the teaching in the specification. See In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990). Paul is directed to expressing small interfering RNA in humans cells using U6 snRNA promoter. Furthermore, the prior art of record teaches that dsRNA longer than 30 base pairs trigger generalized cellular response through activation of dsRNA-dependent protein kinases (Manche et al. Molecular and Cellular Biology 12: 5238-5248, 1992, of record

IDS filed on 6/30/05 and Minks et al. The Journal of Biological Chemistry 254: 10180-10183, 1979). Thus, the property was well known in the prior art.

Claims 172, 176-188, 190-197, 200, 202-209, and 211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al (WO 94/01550, cited on an IDS) in view of Kool (US 5,514,546, cited on an IDS) and Cowsert et al. (US 5,580,767, of record).

Agrawal taught self-stabilizing RNA molecules comprising a region that is complementary to a target in a eukaryotic mRNA in a human cell and a region that is self-complementary. See abstract; page 8, lines 7-11 and 22-24, paragraph bridging pages 11 and 12, and page 13, lines 25-30. The target hybridizing region is from 8 to 50 nucleotides in length (sentence bridging pages 9 and 10). The size of the self complementary region may vary, but may be so extensive as to involve every nucleotide of the oligonucleotide, i.e. it may be 8-50 nucleotides in length (see page 15, lines 3-6, 16-21, and 26-30). The resulting RNA may form a hairpin structure comprising a loop, see page 15, lines 12-16, and Fig. 1. The loop is considered to be a "stuffer" sequence. Thus, Agrawal fairly taught a double stranded RNA comprising a target hybridizing region of 8-50 ribonucleotides, a loop, and a self-complementary region of 8-50 nucleotides. In addition, Agrawal teaches nucleotide and non-nucleotide linkers that would connect the two nucleotide sequences (pages 14-17). The target gene may be a viral gene. Disclosed viruses include human immunodeficiency virus, Yellow Fever virus (a single strand (+) RNA virus), and Herpes simplex virus (a double stranded DNA

virus). See paragraph bridging pages 10 and 11. Absent evidence of unexpected results, it would have been obvious to one of ordinary skill in the art to vary the length of the unpaired loop sequence of the self-stabilizing RNA of Agrawal in order to optimize hybridization of the complementary section of the oligonucleotides, thereby providing increased stability against nucleolytic attack. However, Agrawal does not explicitly teach vectors encoding the antisense oligonucleotides, oligonucleotides targeting a coding region, or liposome-containing compositions.

However, at the time the invention was made, Kool taught delivery of stem-loop oligonucleotides by expression vector or by direct application of the oligonucleotides. See abstract; Fig. 1; column 3, lines 16-19 and lines 58-62; column 4, lines 6-17; and column 14, lines 39-. Kool also disclosed antisense inhibition by targeting coding regions. See column 7, lines 43-46. Kool also disclosed delivery of expression vectors by viral- or liposome-mediated transfection. See column 15, lines 36-45; column 16, lines 43-47; paragraph bridging columns 24 and 25; and column 29, lines 32 and 33.

In addition, at the time the invention was made, Cowsert teaches antisense for inhibiting RNA polymerase (column 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to deliver the oligonucleotides of Agrawal by use of the expression vector of Kool and inhibiting viral RNA polymerase taught by Cowsert. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process

for another is not necessary to render such substitution obvious. Thus the delivery techniques of Kool, i.e. direct application of oligonucleotides, and transfection of oligonucleotide expression vectors, are considered to be exchangeable equivalents. Alternatively, the method of delivering the oligonucleotides can be viewed as a matter of design choice. Moreover, one would have been motivated to use the expression vector of Kool in order to obtain continuous synthesis and action of oligonucleotides for the amount of time that the vector was present in the cell. Generally, expression vectors can be made with selectable markers that allow their maintenance in a cell for a longer time than the expected lifetime of an oligonucleotide. Thus, one of ordinary skill in the art could reasonably expect to obtain antisense inhibition for a longer period of time with the expression vector of Kool.

It would have been similarly obvious to target coding regions of target genes, and to deliver the vectors by viral or liposomal means as suggested by Kool. See KSR v. Teleflex, Id.,

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/14/08 have been fully considered but they are not persuasive.

In response to applicant's argument that the "loop" of Agrawal cannot be construed to read on a "loop" of the claimed invention because the loop of Agrawal (also see Exhibit F) is directed to a single-stranded segment, the argument is not found persuasive because while it is acknowledged that Agrawal on its own does not teach

double stranded construct, however, Agrawal is combined with Kool and Cowsert to make obvious the double stranded nucleotide construct that when expressed would result in a dsRNA comprising a first nucleotide sequence that targets a region of a viral polymerase and a second nucleotide sequence complementary to the first nucleotide sequence. In addition, Agrawal teaches nucleotide and non-nucleotide linkers that would connect the two nucleotide sequences (pages 14-17). Thus, the double stranded construct would contain the stuffer fragment of the claimed product.

In response to applicant's argument that Agrawal, Kool and Cowsert do not teach repeating sequences of only 20-30 consecutive nucleotides identical to the target, the argument is not found persuasive because Agrawal teaches a double stranded RNA comprising a target hybridizing region of 8-50 ribonucleotides, a loop, and a self-complementary region of 8-50 nucleotides. "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists." See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); Also see In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Applicants' argument directed to Paul teaching an unexpected property of the claimed invention is not found persuasive because the citation of lines 6-8 of the abstract of Paul is directed to another reference that teaches using siRNA duplexes, not double-stranded synthetic gene as claimed. The unexpected result has to commensurate in scope with the teaching in the specification. See In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990). Paul is directed to expressing small interfering RNA in humans cells using U6 snRNA promoter.

Furthermore, the prior art of record teaches that dsRNA longer than 30 base pairs trigger generalized cellular response through activation of dsRNA-dependent protein kinases (Manche et al. Molecular and Cellular Biology 12: 5238-5248, 1992, of record IDS filed on 6/30/05 and Minks et al. The Journal of Biological Chemistry 254: 10180-10183, 1979). Thus, the property was well known in the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, 5, 6, 11, 13-15, and 19-22 of U.S. Patent No. 6,573,099. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both set of claims embrace an isolated genetic construct comprising at least two copies of a structural gene sequence, wherein the structural gene sequence comprise a nucleotide sequence which is identical to at least a region of said target gene, wherein at least two copies of the structural gene sequence are placed under the control of a promoter, wherein one or more copies is placed operably in the sense orientation under the control of at least one promoter. With respect to the term stuffer and target gene, one of ordinary skill in the art would look to the specification to construe the scope of the claimed invention and locate the limitations not specifically recited in the claims of '099, but in the instant claims.

Applicant's arguments filed 4/18/08 have been fully considered but they are not persuasive.

Applicant request rejection be held in abeyance until allowable subject matter in the instant application.

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48, 107, 110, 111, 114-136, 138, and 146-149 of copending Application No. 10/646,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene construct comprising a single promoter operably linked to at least two structural genes comprising greater than 20 consecutive nucleotides that are identical to a nucleotide sequence from an animal cell, wherein one structural gene is in the sense

orientation to the promoter and another structural gene is placed in an antisense orientation to the promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Applicant request rejection be held in abeyance until allowable subject matter in the instant application.

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56, 60, 62, 65-101 and 107 of copending Application No. 09/646,807. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene construct comprising a single promoter operably linked to at least two structural genes comprising greater than 20 consecutive nucleotides that are identical to a nucleotide sequence from an animal cell, wherein one structural gene is in the sense orientation to the promoter and another structural gene is placed in an antisense orientation to the promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Applicant request rejection be held in abeyance until allowable subject matter in the instant application.

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34 and 88-133 of copending Application No. 10/821,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene construct comprising a single promoter operably linked to at least two structural genes comprising greater than 20 consecutive nucleotides that are identical to a nucleotide sequence from an animal cell, wherein one structural gene is in the sense orientation to the promoter and another structural gene is placed in an antisense orientation to the promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Applicant request rejection be held in abeyance until allowable subject matter in the instant application.

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44, 77-100, 102, 104-113, and 142-144 of copending Application No. 10/821,710. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene construct comprising a single promoter operably linked to at least two structural genes comprising greater than 20 consecutive nucleotides that are identical to a nucleotide sequence from an animal cell, wherein one structural gene is in the sense

orientation to the promoter and another structural gene is placed in an antisense orientation to the promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
Applicant request rejection be held in abeyance until allowable subject matter in the instant application.

Claims 172, 176-188, 190-197, 199, 200, 202-209, and 211 are directed to an invention not patentably distinct from claims 56, 60, 62, 65-101 and 107 of commonly assigned US application 09/646,807. Specifically, for the reasons set forth under the provisional obviousness double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US applications, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.
Applicant request rejection be held in abeyance until allowable subject matter in the instant application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number 571-272-

0764. The examiner can normally be reached on from 6:30 to 4:00 (Eastern Standard Time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Brian Whiteman/
Primary Examiner, Art Unit 1635